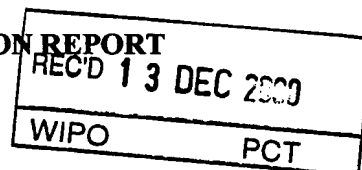


PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference GA 263 PCT	FOR FURTHER ACTION		See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/SE99/01541	International filing date (day/month/year) 06.09.1999	Priority date (day/month/year) 10.09.1998	
International Patent Classification (IPC) or national classification and IPC ₇ A61M 1/36, A61M 5/36 // G01N 21/85			
Applicant GAMBRO AB ET AL.			

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 03.04.2000	Date of completion of this report 05.12.2000
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. 08-667 72 88	Authorized officer Patrik Blidefalk/AE Telephone No. 08-782 25 00

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE99/01541

I. Basis of the report

1. With regard to the **elements** of the international application:*

- ☒ the international application as originally filed
- ☐ the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the claims:
pages _____, as originally filed
pages _____, as amended (together with any statement) under article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the drawings:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.These elements were available or furnished to this Authority in the following language English which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☒ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheet/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2 (c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item I and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE99/01541

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	<u>1-13</u>	YES
	Claims		NO
Inventive step (IS)	Claims	<u>1-13</u>	YES
	Claims		NO
Industrial applicability (IA)	Claims	<u>1-13</u>	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Invention and Background

The invention relates to a method and an apparatus for simultaneous detection of a fluid conduit and characterisation of the fluid in the fluid conduit. This is achieved by arranging a source of light and two optical sensors around the fluid conduit. One sensor detects the presence of a fluid conduit by detecting radiation reflected from the conduit, and the other sensor detects radiation transmitted through the fluid conduit, thereby giving information about the fluid characteristics. The apparatus can for example be used as a monitor in a dialysis system.

Prior art

The prior art, cited in the International Search Report, consists of the following documents:

D1: US 5680111 A
D2: US 3998551 A
D3: US 4830194 A
D4: EP 0467805 A1

D1 reveals a device for detection of air in a fluid conduit. Two light receivers are arranged at 90° and 180° angles in relation to a light source transmitting a beam through a fluid conduit. A processor determines the presence or absence of air in the line based on the combination of the outputs from the two receivers (see column 3, line 28-line 53; column 6, line 35-line 52 and Figure 3.)

In D2, a device for determining the colour of a fluid is described. A detector with a light source and two sensors, one for reflected light and one for transmitted light, is immersed in a liquid and the sensor values are used to determine the colour of the fluid (see the abstract and Figure 2.) .../...

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Box V

D3 describes a granule inspection apparatus in which granules are illuminated from two directions and a sensor detects the amount of light transmitted through, and reflected by, the granules (see the abstract and Figures 1 and 13.)

D4 discloses equipment for detecting the presence of a tube and its contents. A light emitting diode (LED) transmits light towards the tube and an optical sensor detects the amount of light transmitted through the tube. A test procedure is used to check that a tube is present before the characterisation of the tube contents begins. In the test procedure, the sensor signal when no tube is present, i.e., when all the light from the LED reaches the sensor, is stored and subsequently used as a threshold value. Also, during the characterisation of the fluid in the tube, an electromechanical switch indicates the presence or absence of the tube.

Statement of reasons

The most relevant documents cited in the International Search Report are D1 and D4, which disclose arrangements for detection of fluid characteristics in fluid conduits and the presence of the fluid conduit itself (D4). Neither D1 nor D4 reveals an apparatus or method for detecting the presence of a fluid conduit by detecting radiation reflected by the fluid conduit. Furthermore, D2 and D3 disclose detection of reflected light with the intention to study the quality of a granule or detect a colour of a liquid, not to detect the presence of a fluid conduit. A combination of these documents with D1 or D4 would not lead a person skilled in the art towards the present invention, and is therefore not relevant. Thus, claims 1 and 12 are considered to meet the criteria of novelty, inventive step and industrial applicability. Consequently, dependent claims 2-11 and 13 also fulfil these three criteria.

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

To: <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> Gambro Lundia AB Patent Department P.O. Box 10101 220 10 LUND </div> <div style="width: 45%; text-align: right;"> ANKOM 2000 -12- 1 2 </div> </div>		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; padding: 2px;">Date of mailing (day/month/year)</td> <td style="width: 50%; padding: 2px; text-align: center;">08-12-2000</td> </tr> </table>	Date of mailing (day/month/year)	08-12-2000
Date of mailing (day/month/year)	08-12-2000			
Applicant's or agent's file reference GA 263 PCT	IMPORTANT NOTIFICATION			
International application No. PCT/SE99/01541	International filing date (day/month/year) 06-09-1999	Priority date (day/month/year) 10-09-1998		
Applicant GAMBRO AB et al				

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/ Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. 08-667 72 88	<table style="width: 100%;"> <tr> <td style="width: 50%;"> Telex 17978 PATOREG-S </td> <td style="width: 50%; text-align: right;"> Hediye Güzel </td> </tr> <tr> <td colspan="2"> Authorized officer Telephone No. 08-782 25 00 </td> </tr> </table>	Telex 17978 PATOREG-S	Hediye Güzel	Authorized officer Telephone No. 08-782 25 00	
Telex 17978 PATOREG-S	Hediye Güzel				
Authorized officer Telephone No. 08-782 25 00					

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference GA 263 PCT	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/SE99/01541	International filing date (<i>day/month/year</i>) 06.09.1999	Priority date (<i>day/month/year</i>) 10.09.1998
International Patent Classification (IPC) or national classification and IPC ₇ A61M 1/36, A61M 5/36 // G01N 21/85		
Applicant GAMBRO AB ET AL.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 03.04.2000	Date of completion of this report 05.12.2000
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. 08-667 72 88	Authorized officer Patrik Blidefalk/AE Telephone No. 08-782 25 00

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE99/01541

I. Basis of the report**1. With regard to the elements of the international application:***

- ☒ the international application as originally filed
- ☐ the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the claims:
pages _____, as originally filed
pages _____, as amended (together with any statement) under article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the drawings:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.These elements were available or furnished to this Authority in the following language English which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☒ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheet/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2 (c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item I and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE99/01541

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims	<u>1-13</u>	YES
	Claims	_____	NO
Inventive step (IS)	Claims	<u>1-13</u>	YES
	Claims	_____	NO
Industrial applicability (IA)	Claims	<u>1-13</u>	YES
	Claims	_____	NO

2. Citations and explanations (Rule 70.7)**Invention and Background**

The invention relates to a method and an apparatus for simultaneous detection of a fluid conduit and characterisation of the fluid in the fluid conduit. This is achieved by arranging a source of light and two optical sensors around the fluid conduit. One sensor detects the presence of a fluid conduit by detecting radiation reflected from the conduit, and the other sensor detects radiation transmitted through the fluid conduit, thereby giving information about the fluid characteristics. The apparatus can for example be used as a monitor in a dialysis system.

Prior art

The prior art, cited in the International Search Report, consists of the following documents:

D1: US 5680111 A
D2: US 3998551 A
D3: US 4830194 A
D4: EP 0467805 A1

D1 reveals a device for detection of air in a fluid conduit. Two light receivers are arranged at 90° and 180° angles in relation to a light source transmitting a beam through a fluid conduit. A processor determines the presence or absence of air in the line based on the combination of the outputs from the two receivers (see column 3, line 28-line 53; column 6, line 35-line 52 and Figure 3.)

In D2, a device for determining the colour of a fluid is described. A detector with a light source and two sensors, one for reflected light and one for transmitted light, is immersed in a liquid and the sensor values are used to determine the colour of the fluid (see the abstract and Figure 2.) .../...

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE99/01541

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Box V

D3 describes a granule inspection apparatus in which granules are illuminated from two directions and a sensor detects the amount of light transmitted through, and reflected by, the granules (see the abstract and Figures 1 and 13.)

D4 discloses equipment for detecting the presence of a tube and its contents. A light emitting diode (LED) transmits light towards the tube and an optical sensor detects the amount of light transmitted through the tube. A test procedure is used to check that a tube is present before the characterisation of the tube contents begins. In the test procedure, the sensor signal when no tube is present, i.e., when all the light from the LED reaches the sensor, is stored and subsequently used as a threshold value. Also, during the characterisation of the fluid in the tube, an electromechanical switch indicates the presence or absence of the tube.

Statement of reasons

The most relevant documents cited in the International Search Report are D1 and D4, which disclose arrangements for detection of fluid characteristics in fluid conduits and the presence of the fluid conduit itself (D4). Neither D1 nor D4 reveals an apparatus or method for detecting the presence of a fluid conduit by detecting radiation reflected by the fluid conduit. Furthermore, D2 and D3 disclose detection of reflected light with the intention to study the quality of a granule or detect a colour of a liquid, not to detect the presence of a fluid conduit. A combination of these documents with D1 or D4 would not lead a person skilled in the art towards the present invention, and is therefore not relevant. Thus, claims 1 and 12 are considered to meet the criteria of novelty, inventive step and industrial applicability. Consequently, dependent claims 2-11 and 13 also fulfil these three criteria.